REMARKS

Claims 1-5, 10-19, 24-30, and 39 are currently pending and under examination. Claims 7-9, 31-35, 37, 38, and 40 have been cancelled without prejudice. Applicants retain the right to prosecute the same or similar claims in a future continuing application. Claims 1, 10, 15, 24, and 39 have been amended. Unless otherwise noted, the claims have been cancelled or amended to further Applicant's business interests and the prosecution of the present application in a manner consistent with the PTO's Patent Business Goals (PBG; 65 Fed. Reg. 54603 (September 8, 2000), and not in acquiescence to the Examiner's arguments and while reserving the right to prosecute the original (or similar) claims in the future. None of the claim amendments made herein are intended to narrow the scope of any of the amended claims within the meaning of *Festo Corp. v. Shokestu Kinzoku Kogyo Kabushiki Co.*, 234 F.3d 558, 56 USPQ2d 1865 (Fed. Cir. 2000) or related cases.

Claims 1-5, 10-19, 24-30, and 39 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious under U.S. 5,760,082 to Cook et al., U.S. 6,159,525 to Lievense et al. in view of WO 97/18320 to Cain et al. Claims 10 - 19 and 24 - 34 are also rejected under the judicially created doctrine of obviousness-type double patenting. Applicants will submit a terminal disclaimer upon resolution of the §103(a) rejection.

The Examiner maintains that claims 1-5, 10-19, 24-30, and 39 are obvious under the combination of U.S. 5,760,082 to Cook et al. and 6,159,525 to Lievense et al. in view of WO 97/18320 to Cain et al.

A *prima facie* case of obviousness requires the Examiner to provide a reference(s) which (a) discloses all of the elements of the claimed invention, (b) suggests or motivates one skilled in the art to combine the claimed elements to produce the claimed combination, and (c) provides a reasonable expectation of success should the claimed combination be carried out. Failure to establish any one of these three requirements precludes a finding of a *prima facie* case of obviousness and without more entitles the Applicants to allowance of the claims in issue.[1] In addressing this rejection, Applicants focus on the independent claims since the non-obviousness of independent claims necessarily leads to the non-obviousness of claims dependent thereon.[2]

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1 *See, e.g., Northern Telecom Inc. v. Datapoint Corp.*, 15 USPQ2d 1321, 1323 (Fed. Cir. 1990).

2 §MPEP 2143.03.

Applicants respectfully note that the Examiner has correctly set out the analysis in *Graham v. Deere*. However, the Applicants also respectfully note that the Office is required to make a *prima facie* case of obviousness as outlined above and in their previous response, Applicants argued that the Examiner did not establish such a prima facie of obviousness. Thus, stating that Applicants did not address the third prong of the *Graham v. Deere* analysis is not accurate. Applicants respectfully assert that the Examiner failed establish a prima facie case of obviousness both with respect to the previously pending claims and the claims as amended.

In particular, the currently amended claims require that the claimed compositions comprise at least one antioxidant and at least one metal ion chelator. The prior art references cited by the Examiner do not teach or suggest the necessity of using both types of compounds to stabilize CLA compositions against breakdown.

In support of this argument, the Applicants submit herewith the Declaration of Asgeir Sæbo, one of the inventors. As indicated in the Declaration, Natural ASA commissioned scientists at MATFORSK (the Norwegian Food Research Institute), to conduct tests on the stability of CLA compositions. These tests show that CLA compositions stabilized with both an antioxidant and metal ion chelator are superior in terms of VOC levels to compositions treated with citric acid alone.

Furthermore, Applicants direct the Examiner to the report by MATFORSK, which discusses various issues relating to CLA breakdown into VOCs. The report indicates that "we have analyzed CLA-products with regard to volatile oxidation products several times, and the results generally shows that CLA contain large amounts of volatiles compared to oils normally used in food production." Thus, it is apparent that the prior art methods, which generally used an antioxidant or metal ion chelator only, were insufficient to address the problem of the formation of VOCs in CLA products. Applicants have provided a solution to this problem - the use metal ion chelators in addition to antioxidants. The prior art does not teach teach or suggest this solution. Thus, Applicants respectfully submit that the pending claims are not obvious in view of the prior art of record.

CONCLUSION

All grounds of rejection and objection of the Office Action of April 7, 2004 having been

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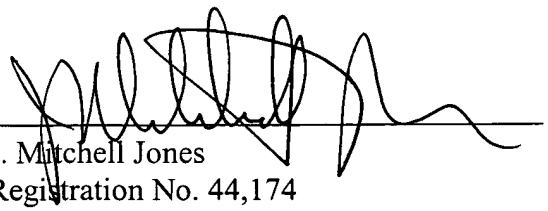
CONCLUSION

All grounds of rejection and objection of the Office Action of April 7, 2004 having been

addressed, reconsideration of the application is respectfully requested. It is respectfully submitted that the invention as claimed fully meets all requirements for patentability and that the claims are worthy of allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicants encourage the Examiner to call the undersigned collect at (608) 218-6900.

Dated: October 6, 2004



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San Francisco, California 94105

PATENT
Attorney Docket No. **CONLINCO-04284**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Asgeir Sæbo *et al.*		
Serial No.:	09/544,004	Group No.:	1617
Filed:	04/06/00	Examiner:	Wang
Entitled:	**CONJUGATED LINOLEIC ACID COMPOSITIONS**		

Declaration of Asgeir Sæbo

Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8(a)(1)(i)(A)

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is, on the date shown below, being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 2231301450

Dated: 10-6-04 By: /M E Wade/

I, Asgeir Sæbø, state as follows:

1. My present position is R&D Manager, Vice President of Natural ASA.

2. I have reviewed the above captioned patent application, of which I am an inventor, the Office Action mailed April 7, 2004, and the Cook, Lievense, and Cain patents cited as prior art.

3. After review of the cited references, I conclude that the references do not teach or suggest the use of both metal chelators and peroxide scavengers to stabilize CLA.

4. Lipid oxidation is the result of many complex free radical reactions. Hydroperoxides are the primary oxidation products. According to the literature, hydroperoxides do not have any odor or flavor. However, hydroperoxides easily decompose to secondary oxidation products, of which some are volatile components with low sensory threshold values. These compounds may have a large impact on the sensory perception of oils or food products even in very low concentrations.

Highly unsaturated oils (e.g. fish oils and probably also CLA) may contain large amounts of volatile oxidation products even if the peroxide values are low. Thus, the oxidative status of such oils should not be assessed based on peroxide values alone. Scientists at MATFORSK (the Norwegian Food Research Institute), have analyzed volatile lipid oxidation products with various headspace/GC-MS techniques (personal communications). In their experience, this is undoubtedly one of the best techniques for assessment of the oxidative quality of fats, oils and foods. Data from such analyses generally correlates with sensory perception of rancidity.

5. Oils that are used in foods are mostly fully refined and deodorized. It is usually required that they have a neutral, bland odor and flavor with no hints of rancidity, i.e. they must have low levels of volatile oxidation products. Oil processing normally removes volatile oxidation products and other unwanted components, yielding oils with very low levels of volatile compounds. However, scientists at MATFORSK have analyzed CLA-products with regard to volatile oxidation products several times, and the results generally shows that CLA contains large amounts of volatiles compared to oils normally used in food production. Their recent experiments also indicate that CLA are very susceptible to oxidation when exposed to air and light.

6. At my request, scientists at MATFORSK (Norwegian Food Research Institute) conducted an experiment to analyze oxidation of CLA . A preparation of CLA was separated in 3 different samples. To sample A, a commercial mixture of antioxidants and metal chelators were added. A metal chelator was added to sample B and sample 3 was kept as reference sample. Samples were placed in a petri dish with air head space at 25C. Samples for analysis were withdrawn at 0, 24, and 48 hours. For analysis, a 3g aliquot of CLA together with an internal standard (ethylheptanate in soy bean oil) was measured into a flask and flushed with nitrogen (100 ml/min) for 15 minutes at room temperature to remove oxygen containing air. The closed vessel was thereafter placed in a water bath at 70C for 15 minutes. Volatile components that were released were trapped on adsorbent tube containing Tenax GR. Two parallels were run on each sample. The volatiles trapped were then desorbed at 250 C for 5 minutes in a Perkin Elmer ATD 400 and transferred to Agilent 6890 Gas Chromatograph with a Agilent 5973 MS Detector (El,70eV). Volatile components were separated on a DB-WAX coloumn from J&W Scientific,

0.25mm i.d.,0,5um, 30 m, with Helium 999.9999% as carrier. The temperature program was 30°C for 10 minutes and then 1°C min^{-1} to 40°C, 3°C min^{-1} to 70°C, and 6.5°C min^{-1} to 230°C with a final holpup time of 5 minutes. Peak integrations and identifications were performed using a HP Chemstation (G1701CA version C.00.00, Agilent Technologies), Wiley 130K Mass Spectral Database (HP 61030A MS Chemstation, John Wiley and sons, Inc.) and NIST98 Mass Spectral Library med Windows Search Program (version 1.6d, US Secretary of Commerce, Gaithersburg, MD).

Upon sampling aliquots for analysis, the samples collected at 24 and 48 hours had a noticeably stronger smell than sample 1. This corresponds to the observed development of volatiles in the samples. The antioxidant mixture very strongly prevented the oxidation of CLA, whereas addition of a few ppm citric acid as metal chelator had only a minor effect. Measured as area count, the volatile heptanal was between 694 and 883 initially but amounted to 3605 and 14592 after 24 and 48 hours respectively if no antioxidant was added. Adding citric acid (normally only around 25 ppm is soluble in oil) reduced corresponding values to 3350 and 12701 and adding a commercial mixture containing metal chelators and other antioxidants reduced the values to 853 and 1131 respectively. The same pattern was observed for the volatiles hexanal, 2-octenal, 2-nonenal, 2.4-octadienal and several others. In conclusion, volatiles developed extremely fast in samples not containing a proper antioxidant mixture.

10. Based on above mentioned experiment and numerous reports earlier produced at Norwegian Food Research Institute, I asked for their opinion on feasibility of adding CLA oils to food items. Their response is added for reference at Tab 1.

11. I further declare that all statement made herein of my own knowledge are true and that all state nents made on information and belief are believed to be true; and further that these state nents were made with the knowledge that willful false statements and the like so made are puni: hable by fine or imprisonment, or both, under section 1001 of title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Asgeir Sæbø

Date: Oct. 5th. 2004

OPPDRAGSRAPPORT

MATFORSK - Norsk institutt for næringsmiddelforskning

Osloveien 1, 1430 Ås
Tlf. 64 97 01 00

Rapportnummer:
O-7834-42 **Preliminær**
Tilgjengelighet: Fortrolig

Rapportens tittel:	**Dato:**
CLA i mat	01.09.04
Prosjektleder/forfatter:	**Prosjektleders signatur:**
Anne S. Jørgensen/Gjermund Vogt/Elisabeth Olsen	
Avdelingsleder:	**Avdelingsleders signatur:**
Ellen Merethe Magnus	
Avdeling:	**Prosjektnummer:**
Produkt og råvarekunnskap	O-7834
Oppdragsgiver:	**Oppdragsgivers ref:**
Natural ASA	Asgeir Sæbø

Sammendrag/ekstrakt:

We have been asked by Asgeir Sæbø, Natural ASA, to give our general opinion on use of CLA as an additive to foods. This statement refers to the oxidative stability of CLA only, and is based on our general knowledge of lipid oxidation. Health implications and other aspects of such use are not considered.

We have been asked by Natural ASA to give our general opinion on use of CLA as an additive to foods with regard to oxidative stability.

Scientists at MATFORSK, the Norwegian Food Research Institute, have worked with issues regarding oxidative stability of fats and oils for many years. Simple model systems as well as complex food products have been studied. We have participated in several projects with other institutes, e.g. "Optimal methods for analysis of rancidity in foods" and "Lipid quality and oxidation of polyunsaturated fatty acids in foods with marine lipids", and we often perform analyzes for the food industry. The following is based on our general knowledge and experience.

Lipid oxidation is the result of many complex free radical reactions. Hydroperoxides are the primary oxidation products. According to the literature, hydroperoxides do not have any odor or flavor. However, hydroperoxides easily decompose to secondary oxidation products, of which some are volatile components with low sensory threshold values. These compounds may have a large impact on the sensory perception of oils or food products even in very low concentrations. Highly unsaturated oils (e.g. fish oils and probably also CLA) may contain large amounts of volatile oxidation products even if the peroxide values are low. Thus, the oxidative status of such oils should not be assessed based on peroxide values alone. At MATFORSK, we have analyzed volatile lipid oxidation products with various headspace/GC-MS techniques for more than 10 years, and in our experience, this is undoubtedly one of the best techniques for assessment of the oxidative quality of fats, oils and foods. Data from such analyses generally correlates with sensory perception of rancidity.

Oils that are used in foods are mostly fully refined and deodorized. It is usually required that they have a neutral, bland odor and flavor with no hints of rancidity, i.e. they must have low levels of volatile oxidation products. Oil processing normally removes volatile oxidation products and other unwanted components, yielding oils with very low levels of volatile compounds. However, we have analyzed CLA-products with regard to volatile oxidation products several times, and the results generally shows that CLA contain large amounts of volatiles compared to oils normally used in food production. A recent experiment also indicates that CLA are very susceptible to oxidation when exposed to air and light. This leads to the assumption that use of CLA as an ingredient in food products may lead to deterioration of the product quality.

In our opinion, if CLA are to be utilized as an ingredient in food products, the oil needs to have a higher oxidative quality from the start and it must be stabilized against oxidation. Precautions against oxidation should be taken from start to finish in the production process for the oil as well as the food product. Such precautions could be addition of antioxidants as early as possible in the process, no exposure to air or light, and storage at as low temperatures as possible. We would also highly recommend thorough pre-trials to investigate the shelf life of the actual product under "normal" storage conditions before release.